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EXAMINER	
MICHENER, JENNIFER KOLB	
ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/879,216	RICHARD, ROBERT E.
	Examiner	Art Unit
	Jennifer K Michener	1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 21-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The objection to the drawings is withdrawn.

Claim Objections

2. Claim 21 is objected to because of the following informalities: an independent claim should be directed to "A method", not "The method". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The new matter rejection of claims 1-15 under 35 U.S.C. 112, first paragraph, has been withdrawn based on Applicant's amendment.

Based on Applicant's amendments, the following new 112, 1st rejection is applied:

4. Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for coating, does not reasonably provide enablement for treating. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification is limited to coating medical devices with a therapeutic agent by exposing to a therapeutic agent interfaced with a supercritical fluid and transferring the therapeutic agent to the medical device. The claims, as

written, require only *treating* the medical device by exposing to supercritical fluid interfaced with the therapeutic agent. There is no active step of coating the medical device with the therapeutic agent. Therefore the claims are open to merely swelling the medical device with the supercritical fluid and never depositing the entrained therapeutic agent, as outlined in the previous office action. This interpretation is broader than the enabling disclosure. In the previous office action, Examiner provided suggestions and interpretations based on her review of the specification. In response, Applicant disagreed with Examiner's assertions, stated that the claims were not to be read in light of the specification, and broadened the language of the claim to "treating", which is broader than disclosed by the specification.

To overcome this rejection, Examiner kindly suggests changing the preamble language back to "coating" and adding an active coating step in the exposing step, as outlined in the previous office action.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-15 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (6,153,252) in view of Subramaniam et al. (5,833,891).

Examiner maintains the rejection of claims 1-15.

Rejections of newly-added claims 21-22 are included herein, as necessitated by Applicant's amendments.

Regarding the newly-added limitation of claim 1 requiring "transporting the interfaced therapeutic and supercritical fluid towards the medical device", Examiner notes that in Figure 2, Subramaniam shows supercritical carbon dioxide (126), therapeutic solution (146), and energizing gas (127) flowing towards the medical device. After exiting the nozzle (124) the therapeutic interfaces with the supercritical fluid and, until the supercritical fluid depletes the dispersant and precipitates the therapeutic agent (col. 6, lines 53-55), they will continue to flow, together, towards the medical device, as required by the claim.
Additionally and alternatively, Subramaniam teaches that the energizing gas, which is propelled from the nozzle together with the therapeutic solution towards the substrate, may be supercritical carbon dioxide (col. 11, lines 6-13 and Fig. 2).

Regarding the newly-added limitations of claims 12 and 15, Hossainy teaches the use of a primer coating before coating the medical devices with the polymer-therapeutic layer (col. 7, lines 15-17). This would act as the coating of claim 12 that is exposed to the supercritical fluid. As outlined in the previous office action, the first quantities of supercritical fluid used, prior to precipitation, would swell the primer coating.

Regarding newly-added claim 21 containing the limitations of claim 7, addressed in the previous office action, Examiner notes that Subramaniam teaches that the solute-depleted *liquid* organic solvent and solvent-loaded carbon dioxide are removed from the chamber via outlet 122 and metering valve 154 (col. 11, lines 14-16). Looking at Figure 2, it is seen that outlet 122 is more than halfway up the chamber wall, well above the exit port of the nozzle and the substrates to be coated. Since Subramaniam teaches an active step of removing liquid or liquid-like substances from such an elevated exit port, it is Examiner's position that this solution is not passively removed. Examiner maintains that it would have been obvious to one of ordinary skill in the art desiring to move a solution, from the chamber to a recovery station, to use a pump. Pumps inherently create a vacuum pressure as necessary to draw the solution along the exit line.

Regarding newly-added claim 22 containing the limitations of claim 9, addressed in the previous office action, Examiner maintains her assertion that recycling expensive therapeutic agents would have been obvious. The claim specifically requires collecting the supercritical fluid after transferring the therapeutic from the fluid to the medical device and thereafter removing the residual therapeutic from the fluid. Examiner notes that Subramaniam inherently collects the supercritical fluid as it exits outlet 122 and flows through the metering valve (Figure 2). The supercritical carbon dioxide is subsequently separated from the therapeutic-depleted organic solvent (col. 11, lines 14-20), at which point the residual therapeutic is removed from the supercritical fluid, as required by the claim, because it remains in the organic solvent, as evidenced by

Subramaniam's testing of the solvent for remaining drug and polymer content (col. 10, line 9).

As necessitated by Applicant's removal of the new matter, the following rejections are re-applied:

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Greiner (EP 0 405 284 A2).

Greiner teaches a method of coating a catheter medical device comprising creating a saturated solution of a pharmaceutical in a supercritical fluid and contacting the saturated solution to a medical device, wherein a subsequent reduction of pressure transfers the pharmaceutical from the supercritical fluid to the medical device (abstract; paragraph bridging columns 1 and 2). The solution must inherently be transported to the device to be coated in order to coat the device.

Regarding claim 4, Greiner teaches immersion of the catheter in the saturated solution, which would qualify as a exposing the catheter to a "bath" of the solution (col. 1, line 55).

Regarding claim 5, the therapeutic dissolves in the supercritical fluid, as stated above.

Regarding claim 6, it appears that the solution of Greiner meets the definition of a colloid, in that particles of the agent are mixed with a solvent to form the solution.

Claim Rejections - 35 USC § 103

9. Claims 3, 7, 9, 11, and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner.

Greiner teaches that which is disclosed above.

While Greiner teaches immersion of the medical device into the therapeutic solution, he fails to specifically teach spraying of the solution onto the medical device. However, it is Examiner's position that the interchangeability of dipping and spraying as coating techniques is well-known in the art of chemical coating. It would have been obvious to one of ordinary skill in the art to substitute one method for another with the expectation of similar, successful results because both methods are known to provide uniform coatings in a simple manner.

Regarding claims 7, 9, and 21-22 Greiner fails to specifically teach separating the excess therapeutic agent from supercritical fluid.

First, Examiner notes that maintenance of a supercritical fluid at supercritical temperature and pressure inherently requires the use of a coating chamber.

Regarding the collection operation, Examiner notes that Greiner's method of immersing a catheter into a saturated solution of a therapeutic agent will not result in attachment of all therapeutic agent that is present in solution to the surface of the catheter. After immersion, excess supercritical fluid, with therapeutic agent dissolved there, will remain. Due to the high expense of pharmaceutical products, it is Examiner's position that one of ordinary skill in the art would collect the excess solution to recover the expensive pharmaceutical agents therein for a subsequent coating operation, as required by the claims. In recovering the solution from the coating chamber, a pump would be required to move the solution, which inherently draws a vacuum. The use of a pump would have been obvious to one of ordinary skill in the art desiring to move the solution from the chamber to a recycling location.

Regarding claim 11, Greiner teaches a wide variety of catheter substrates to be coated in the method of his invention, including those used in the cardiovascular system, which appear to be "angio-catheters" or those which are inserted peripherally to be used centrally, as required by the claim.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner in view of Hossainy (US 6,153,252).

Greiner teaches that which is disclosed above. Additionally, Greiner teaches the use of supercritical carbon dioxide as the fluid of his invention, as is required by claim 10. Greiner further teaches the use of such pharmaceutical therapeutic agents as antibiotics

and growth factors (col. 4), among many. However Greiner fails to specifically teach the use of the specific paclitaxel agent required by Applicant.

Hossainy teaches the use of antibiotics, growth factors, and paclitaxel, among others, as coatings for implantable medical devices.

Since Greiner and Hossainy teach the use of therapeutic agents on implantable medical devices and Hossainy teaches the suitability of paclitaxel for such a coating, Hossainy would have reasonably suggested the use of paclitaxel as the therapeutic agent for coating onto the medical device of Greiner. It would have been obvious to one of ordinary skill in the art to use the teachings of Hossainy in the method of Greiner to coat Greiner's medical device with paclitaxel because it would have been expected that paclitaxel would serve as a beneficial agent when used *in vivo* on a medical device for controlled elution within the vicinity of the implantable device.

11. Claims 2, 8, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner in view of Cook et al. (US 5,916,585).

Greiner teaches that which is disclosed above regarding the use of supercritical fluid to deposit pharmaceutical agents on implantable medical devices.

What Greiner fails to specifically teach is the use of a carrier coating in addition to the pharmaceutical agent.

Regarding claims 2 and 12, Cook et al. teach coating implantable medical devices, such as vascular grafts or stents, with a hydrophilic polymer layer, followed by a bioactive

species attached to the polymer layer by functional groups (abstract). The polymer layer of Cook acts as a carrier for the bioactive species. The bioactive species may be a drug or pharmaceutical agent (col. 7, lines 17-21; examples 15 and 16).
Since Greiner teaches application of a therapeutic agent onto an implantable vascular device and Cook teaches the use of a polymeric carrier layer to be used in conjunction with a pharmaceutical agent on an implantable vascular graft or stent, Cook would have reasonably suggested the use of a polymer carrier in the method of Greiner. It would have been obvious to one of ordinary skill in the art to use the teachings of Cook in the method of Greiner because it would have been expected that the use of Cook's carrier layer would have provided the device of Greiner with a more firmly attached pharmaceutical agent and a more hydrophilic coating.

Regarding claim 8, Cook additionally teaches the use of supercritical carbon dioxide as a suitable solvent for application of the hydrophilic polymer carrier layer of his invention. Cook is combinable with Greiner for those reasons outlined above regarding claims 2 and 12. Additionally, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to apply Cook's polymer carrier layer in supercritical carbon dioxide at the same time as Greiner's pharmaceutical agent in supercritical carbon dioxide with the expectation of successful results because the combined teachings of Greiner and Cook indicate that supercritical carbon dioxide is a suitable solvent for the polymer carrier layer and the pharmaceutical agents of their inventions. It would have been obvious to one of ordinary skill in the art to use a single supercritical fluid

processing step for both the carrier and the drug instead of the more time-consuming, thus costlier, 2-step method.

Regarding claims 13-14, Greiner teaches immersion as the application technique. As outlined above, spraying is an obvious variation of immersion/flooding/dipping in the chemical coating art.

Greiner teaches that the supercritical carbon dioxide solvent acts to swell the polymer catheter substrate of his invention, as is required by claim 15 (abstract).

Response to Arguments

12. Applicant's arguments filed 11/7/2003 have been fully considered but they are not persuasive.

Applicant argues that Subramaniam's anti-solvent method does not transport the interfaced therapeutic and supercritical fluid towards the medical device together, as required by claim 1, or to a previously coated medical device, as required by claim 12. This argument has been addressed above.

Applicant argues that claim 7 was not addressed sufficiently and that the office action is completely silent regarding claim 9.

Examiner disagrees.

Claim 7 and new claim 21 ~~has~~ have been addressed above. The previous office action discussed the importance and obviousness of recycling expensive therapeutic agents, as required by claim 9 and new claim 22, and has also been addressed above.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose *new* telephone number is 571-272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer Kolb Michener
January 9, 2004

SHRIVE P. BECK
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